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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,479	12/19/2006	Masayoshi Shichiri	1004331.037US (4439-4047)	9587
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EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

Office Action Summary

Application No.

10/599,479

Applicant(s)

SHICHIRI, MASAYOSHI

Examiner

CHIH-MIN KAM

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 10.11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.5 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1, 5 and 10-15 are pending.

Applicants' amendment filed February 15, 2010 is acknowledged. Applicants' response has been fully considered. Claims 1, 5 and 12-14 have been amended, and claims 2-4 and 6-9 have been cancelled. Claims 10-11 and 15 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1, 5 and 12-14 are examined.

Withdrawn Informalities

2. The previous objection to the abstract is withdrawn in view of applicants' submission of a new abstract, and applicants' response at pages 6-7 in the amendment filed February 15, 2010.

Withdrawn Claim Objections

3. The previous objection to claims 6 and 8 is withdrawn in view of applicants' cancellation of the claims in the amendment filed February 15, 2010.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 2, 4, 7 and 9 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claims in the amendment filed February 15, 2010.

5. The previous rejection of claim 3 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 8 in the amendment filed February 15, 2010.

Withdrawn Claim Rejections - 35 USC § 102

6. The previous rejection of claim 3 under 35 U.S.C. 102(b) as being anticipated by Carulli *et al.* (WO 01/32875), is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 8 in the amendment filed February 15, 2010.

Claim Objections

7. Claim 1 is objected to because of the use of the term "SEQ ID No.:2" in claim 1, parts (B), (C) and (D). Use of the term "SEQ ID NO:2" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 5 and 12-14 are drawn to an isolated peptide consisting of any one of the following amino acid sequence (A) to (F): (A) the amino acid sequence shown by SEQ ID NO:2; (B) the amino acid sequence shown by position 1 to 20 of SEQ ID NO:2; (C) the amino acid sequence shown by position 5 to 24 of SEQ ID NO:2; (D) the amino acid sequence shown by position 2 to 13 of SEQ ID NO:2; (E) an amino acid sequence wherein one to five amino acids are deleted, substituted or added in the sequence shown by any one of (A) to (D), wherein a peptide consisting of the amino acid sequence has a cardioinhibitory activity or hypotensive

activity; and (F) an amino acid sequence having 80% or more homology with the amino acid sequence shown by any one of (A) to (D), wherein a peptide consisting of the amino acid sequence has a cardioinhibitory activity or hypotensive activity; a fusion peptide of the amino acid sequence of any one of (A) to (F) and a marker protein and/or peptide tag; a method of screening a cardioinhibitory factor or hypotensive factor using the peptide; a method of screening an inhibitor of a cardioinhibitory activity or an inhibitor of hypotensive factor using the peptide; and a cardioinhibitory /hypotensive agent comprising the peptide.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that the present invention relates to a peptide consisting of the amino acid sequence of SEQ ID NO:2 and an amino acid sequence related to SEQ ID NO:2 (paragraphs [0009], [0010]), the specification does not sufficiently describe a genus of variants for peptides that have one to five amino acids are deleted, substituted or added, or have at least 80% homology in the sequences of residues 1-20, 5-24 and 2-13 of SEQ ID NO: 2 (i.e., SEQ ID NO:2 fragments), when there is substantial variation within the whole genus of peptides variants. Although the specification discloses specific peptide fragments of SEQ ID NO:2 such as residues 1-20, 5-24 and 2-13 of SEQ ID NO:2 are functional (paragraph [0014]), there is no structure-activity correlation for variants of SEQ ID NO: 2 fragments (i.e., residues 1-20, 5-24 and 2-13 of SEQ ID NO: 2), a skilled artisan cannot predict which variant of the fragment is functional. A few species of SEQ ID NO:2 fragments (e.g., residues 1-20, 5-24 and 2-13 of SEQ ID NO:2) do not provide sufficient written description for the whole genus of variants for SEQ ID NO: 2 fragments. The lack of description on the structure-activity correlation for variants of SEQ ID NO:2 fragments and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate claims 2 and 4 have been cancelled, and claims 5 and 12-14 have been amended to be dependent from allowable claim 1. In light of these claim amendments, the written description is satisfied, applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph (page 7 of the response).

Applicants' response has been considered. Regarding claim 1 and their dependent claims, the arguments are not found persuasive because of the following reasons. The previously claim 1 is directed to the amino acid sequence of SEQ ID NO:2, an amino acid sequence having one to five amino acids being deleted, substituted or added in the sequence of SEQ ID NO:2 and having a cardioinhibitory activity or hypotensive activity; and an amino acid sequence having 80% or more homology to the amino acid sequence of SEQ ID NO:2 and having a cardioinhibitory activity or hypotensive activity, it is not directed to variants of SEQ ID NO:2 fragments such as residues 1-20, 5-24 and 2-13 of SEQ ID NO:2. Furthermore, the specification does not describe the structure-activity correlation for variants of SEQ ID NO: 2 fragments (i.e., residues 1-20, 5-24 and 2-13 of SEQ ID NO: 2), a skilled artisan cannot predict which variant of the fragment is functional. The lack of description of the structure-activity correlation for variants of SEQ ID NO: 2 fragments and the lack of representative species, applicants have failed to sufficiently describe the claimed invention. Therefore, the rejection is maintained.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

May13, 2010